

### **REMARKS**

Claims 1 and 84-115 are currently pending. By the present communication, no claims have been added or canceled, and claim 1 has been amended to correct an apparent grammatical error. Accordingly, upon entry of this paper, claims 1 and 84-115 will be under consideration.

#### **Rejection Under 35 U.S.C. §112, First Paragraph**

Applicants respectfully traverse the rejection of claims 1 and 84-115 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description. The Office Action alleges that the specification fails to provide support for the negative limitation, “wherein the at least one SNP of the second population of SNPs is not located within a region of a gene encoding a protein.” Applicants respectfully direct the Examiner’s attention to paragraph [0330] of the published application (U.S. Pub. No. 2004/0229231), which states, “...most of the SNPs identified herein are non-coding, either silent polymorphisms or residing in the gene proximal promoter, intron or 3’UTR.” Since the SNPs identified in the specification as filed are non-coding, one of skill in the art would understand that such SNPs are not located within a region of a gene encoding a protein. Withdrawal of the rejection is respectfully requested.

#### **Rejections Under 35 U.S.C. §103**

Applicants respectfully traverse the rejection of claims 1, 84-86, 90-97, 99-100 and 104-109 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Parra et al. in view of Cargill et al. The U.S. Supreme Court decision in the *KSR International v. Teleflex Inc.* (82 USPQ2d 1385), modified the standard for establishing a prima facie case of obviousness. Under the *KSR* rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references still has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such

as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references.

The Office Action alleges that Parra teaches a method for inferring the extend of European admixture in six different African-American populations. However, Parra does not teach a first population of SNPs identified from a database in silico, and further does not teach selecting SNPs from a first population to generate a second population of SNPs wherein the at least one SNP of the second population of SNPs have minor allele frequencies >1% and are not located within a region of a gene encoding a protein. The Action relies upon Cargill as allegedly teaching a method for screening samples to determine whether identified SNPs are coding or non-coding SNPs.

Applicants submit that Parra describes the use of linked autosomal markers, mtDNA, and Y-chromosome markers located in gene coding regions in the study of ancestral proportions and admixture dynamics (See, e.g., Abstract; page 19, Col. 2 to page 20, Col. 1). Parra does not describe a second population of SNPs as in claim 1, step c), where the SNP may be correlated with but not linked to a gene-linked trait, wherein the second population of SNPs is an autosomal SNP, and wherein the at least one SNP of the second population of SNPs is not located within a gene encoding region. The markers used in Parra et al. include, for example, apolipoprotein A (APO A), AT3, antithrombin 3 (AT3), DUFFY antigen (FY), tyrosinase mutation (OCA2) and vitamin D binding protein (GC), and are all located within a gene encoding region.

Applicants further submit that the deficiencies in Parra are not cured by Cargill. Cargill indicates that “[t]he genes were chosen because of their potential relevance to common, clinically significant diseases, such as coronary artery disease, type II diabetes and schizophrenia.” (Cargill, page 232, left column). As such, since the intent of Cargill is to “understand the role of common genetic variants in susceptibility to common diseases,” (Cargill, Abstract) Cargill sets out to link a particular phenotype with a genotype, rather than looking at ancestry informative markers (AIMs). As described in the instant specification, “AIMs are genetic loci that show alleles with high frequency differences between populations.” (Published specification at paragraph [0067]). In addition, “there is no requirement that the markers (AIMs)

useful in the present methods be in linkage disequilibrium with a gene/trait and, in fact, AIMs that are disclosed herein as correlating with a trait can be located on different chromosomes from each other and from a gene/locus known to be associated with the trait.” (Published specification at paragraph [0066]).

Accordingly, since the combined references do not teach each and every limitation of the pending claims, one of skill in the art would not have been motivated to combine the reference teachings to arrive at the claimed invention. Absent a motivation to combine the references, one of skill in the art would not have had an expectation of successfully achieving the claimed invention. As such, Applicants respectfully submit that *prima facie* obviousness of the invention over Parra and Cargill, either alone or in combination, has not been shown by the Examiner, and request withdrawal of the rejection.

Applicants respectfully traverse the rejection of claims 1, 84-97, 99-100, and 104-115 under 35 U.S.C. §103(a), as allegedly being unpatentable over Parra et al., in view of Cargill et al., and further in view of Sorenson et al. The arguments set forth above with regard to Parra and Cargill apply equally and are incorporated here. Specifically, Cargill fails to cure the deficiencies of Parra since Cargill focuses on identifying SNPs for the application to disease association.

The Action relies upon Sorenson as allegedly teaching a genealogical research and record keeping system for identifying commonalities in haplotypes from biological samples. However, since Sorenson fails to describe a second population of SNPs as in claim 1, step c), where the SNP may be correlated with but not linked to a gene-linked trait, wherein the second population of SNPs is an autosomal SNP, and wherein the at least one SNP of the second population of SNPs is not located within a gene encoding region, Applicants respectfully submit that Sorenson fails to cure the deficiencies identified in Parra and Cargill.

Accordingly, since the combined references do not teach each and every limitation of the pending claims, one of skill in the art would not have been motivated to combine the reference teachings to arrive at the claimed invention. Absent a motivation to combine the references, one

of skill in the art would not have had an expectation of successfully achieving the claimed invention. As such, Applicants respectfully submit that *prima facie* obviousness of the invention over Parra, Cargill, and Sorenson, either alone or in combination, has not been shown by the Examiner, and request withdrawal of the rejection.

Applicants respectfully traverse the rejection of claims 1, 84-101, and 104-115 under 35 U.S.C. §103(a), as allegedly being unpatentable over Parra et al., in view of Cargill et al., in view of Sorenson et al. and further in view of Shriver et al. The arguments set forth above with regard to Parra, Cargill, and Sorenson apply equally and are incorporated here. Specifically, both Cargill and Sorenson fail to cure the deficiencies of Parra since Cargill focuses on identifying SNPs for the application to disease association, and Sorenson describes a genealogical research and record keeping system for identifying commonalities in haplotypes from biological samples.

The Action relies upon Shriver for allegedly teaching a method for identifying a set of genetic markers using likelihood analysis that allows the confident determination of ethnicity for use in a forensic setting. However, since Shriver fails to describe a second population of SNPs as in claim 1, step c), where the SNP may be correlated with but not linked to a gene-linked trait, wherein the second population of SNPs is an autosomal SNP, and wherein the at least one SNP of the second population of SNPs is not located within a gene encoding region, Applicants respectfully submit that Shriver fails to cure the deficiencies identified in Parra, Cargill, and Sorenson.

Accordingly, since the combined references do not teach each and every limitation of the pending claims, one of skill in the art would not have been motivated to combine the reference teachings to arrive at the claimed invention. Absent a motivation to combine the references, one of skill in the art would not have had an expectation of successfully achieving the claimed invention. As such, Applicants respectfully submit that *prima facie* obviousness of the invention over Parra, Cargill, Sorenson, and Shriver, either alone or in combination, has not been shown by the Examiner, and request withdrawal of the rejection.

Applicants respectfully traverse the rejection of claims 1 and 84-115 under 35 U.S.C. §103(a), as allegedly being unpatentable over Parra et al., in view of Cargill et al., in view of Sorenson et al., in view of Shriver et al., and further in view of Pritchard et al. The arguments set forth above with regard to Parra, Cargill, Sorenson, and Shriver apply equally and are incorporated here. Specifically, Cargill, Sorenson, and Shriver, either alone or in combination, fail to cure the deficiencies of Parra.

The Action relies upon Pritchard for allegedly teaching a method of inferring proportional ancestry of difference ancestral groups in a population structure using a graphical display format. However, since Pritchard fails to describe a second population of SNPs as in claim 1, step c), where the SNP may be correlated with but not linked to a gene-linked trait, wherein the second population of SNPs is an autosomal SNP, and wherein the at least one SNP of the second population of SNPs is not located within a gene encoding region, Applicants respectfully submit that Pritchard fails to cure the deficiencies identified in Parra, Cargill, Sorenson, and Shriver.

Accordingly, since the combined references do not teach each and every limitation of the pending claims, one of skill in the art would not have been motivated to combine the reference teachings to arrive at the claimed invention. Absent a motivation to combine the references, one of skill in the art would not have had an expectation of successfully achieving the claimed invention. As such, Applicants respectfully submit that *prima facie* obviousness of the invention over Parra, Cargill, Sorenson, Shriver, and Pritchard, either alone or in combination, has not been shown by the Examiner, and request withdrawal of the rejection

**Conclusion**

Applicants submit that pending claims 1 and 84-115 are in condition for allowance. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

The Commissioner is hereby authorized to charge the total amount of \$555.00 to Deposit Account No. 07-1896 as payment for a Three-Month Extension of Time fee. No additional fees are believed due in connection with this Response. However, the Commissioner is further authorized to charge any additional fees required by this submission, or make any credits or overpayments, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,



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